

REMARKS

The Office Action of February 10, 2005, has been received and reviewed. Claims 1-17 and 24-38 are currently pending in the application. Claims 10-17 and 24-35 have been withdrawn from consideration as being directed to a non-elected invention. Claims 3, 4, 7 and 37 have been amended, and new claims 39 and 40 have been added as set forth herein. All amendments are made without prejudice or disclaimer. No new matter has been added. Reconsideration is requested.

New Claims 39 and 40

New claims 39 and 40 have been added as set forth herein. Basis for claims 39 and 40 is found, *inter alia*, at page 4, lines 8-9; page 5, lines 12-14 and lines 23-28; page 6, lines 3-6 and lines 19-23; and page 6, line 25 through page 7, line 2. Thus, no new matter has been added.

Objections to the Specification

The Specification was objected to for failing to comply with 37 C.F.R. §§ 1.821-1.825. It was thought that paragraphs [0053], [0054] and [0069] do not disclose the necessary sequence identifiers. An amendment was filed on November 1, 2001, inserting sequence identifiers where appropriate. (*See*, attached copy of the date-stamped postcard acknowledging receipt of the amendment and dated November 1, 2001). Submitted herewith is a courtesy copy of the aforementioned amendment.

Additionally, the specification has been amended to include a CROSS-REFERENCE TO RELATED APPLICATIONS paragraph in accordance with 37 U.S.C. § 1.78(a)(2). The priority claims recited in the CROSS-REFERENCE TO RELATED APPLICATIONS paragraph were acknowledged in the Filing Receipt of February 5, 2002. Thus, no new matter has been added.

Withdrawal of the objections to the Specification is requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 4, 7 and 36-38 stand rejected under 35 U.S.C. § 112, second paragraph, for assertedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (*See*, Office Action of February 10, 2005, page

3). Partly in view of the amendments to claims 3, 4, 7 and 37, reconsideration and withdrawal of the indefiniteness rejections are requested.

It was thought to be unclear “how [an] animal can comprise a pig, a breeding animal or an animal destined for slaughter as ‘comprising’ is open language.” (*Id.*) It was noted that “amending the claims to indicate that the animal ‘is a pig’ ‘is a breeding animal’ or ‘is an animal destined for slaughter’ would obviate this rejection.” (*Id.* at page 4). Although applicants do not agree that claims 3, 4, 7 and 37 are indefinite, claims 3, 4, 7 and 37 have been amended in accordance with the Examiner’s suggestion, and request that the rejections be withdrawn.

Since claims 1 and 36 do not include the recitation of an animal “comprising” a pig, they are not indefinite.

Reconsideration and withdrawal of the indefiniteness rejections of claims 1, 3, 4, 7 and 36-38 are requested.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-9 and 36-38 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement and as assertedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejections as hereinafter set forth.

Written Description Rejections

The Office Action asserted that the “specification does not identify any particular sequence structure or particular function [that] must be conserved, nor is there any disclosure of QTL functional fragments.” (*See, Office Action* at page 6). The M.P.E.P. states “[a]n adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.” (*See, M.P.E.P.*, at § 2163, II, A, 3(a), citing *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000)).

Claim 1 is directed towards a method for selecting an animal for having desired genotypic properties comprising testing the animal for the presence of a parentally imprinted quantitative trait locus. The as-filed specification discloses a “method for selecting a domestic animal for

having desired genotypic or potential phenotypic properties comprising testing said animal for the presence of a parentally imprinted qualitative or quantitative trait locus (QTL).” (Specification, as-filed, page 3, lines 19-23). Thus, one of ordinary skill in the art would conclude that the inventors were in possession of claim 1.

Claims 2-9 and 36-38 comply with the written description requirement, *inter alia*, as depending from a base claim that does not lack written description.

With further regard to claim 2, written description exists in the as-filed specification which indicates “[t]he invention provides testing such a sample for the presence of a nucleic acid wherein a QTL or allele associated therewith is associated with the phenomenon of parental imprinting.” (*Id.* at page 5, lines 23-26).

Written description for claim 3 exists at page 8, lines 33-35 of the as-filed specification indicating that the “QTL is located at a position corresponding to a QTL located at chromosome 2 in the pig.” (*Id.* at page 8, lines 33-35).

Regarding claim 4, the as-filed specification describes “[i]n pigs, said cluster is mapped at around position 2p1.7 of chromosome 2” such that one of ordinary skill in the art would conclude that the inventors were in possession of the invention of claim 4. (*Id.* at page 9, lines 23-25).

Written description for claims 5, 6 and 38 are found at page 9 of the as-filed specification which indicates that the “QTL is related to the potential muscle mass and/or fat deposition ... wherein said QTL comprises at least a part of an insulin-like growth factor-2.” (*Id.* at page 9, lines 29-33).

Claim 7 is supported by the as-filed specification which indicates that “a ny241 (G-A) transversion [is] in the second exon of the porcine IGFII gene and SW9.” (*Id.* at page 14, lines 22-24).

Written description for claim 8 exists by the passage in the as-filed specification stating that the “parentally imprinted quantitative trait locus (QTL) or fragment thereof capable of being predominantly expressed by one parental allele.” (*Id.* at page 16, lines 12-15).

Claim 9 is supported in the passage of the as-filed specification that indicates “recombinant alleles linked with meat quality traits such as intra-muscular fat or muscle mass could be fixed in the dam lines.” (*Id.* at page 21, lines 1-3).

Claim 36 is supported by the as-filed specification reciting “at least a part of the nucleic acid genome of an animal where genetic information capable of influencing said quantitative trait (in said animal or in its offspring) is located.” (*Id.* at page 2, lines 10-13).

Written description for claim 37 exists in the as-filed specification which recites in part “select a breeding animal or animal destined for slaughter, or embryos or semen derived from these animals, for having desired genotypic or potential phenotypic properties.” (*Id.* at page 18, lines 24-27).

Reconsideration and withdrawal of the written description rejections of claims 1-9 and 36-38 are requested.

Enablement Rejections

The Office Action asserted that the Specification “does not reasonably provide enablement for the full breadth of the claims . . . does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.” (*See, Office Action* at page 8). The M.P.E.P., however, indicates that “[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied.” (M.P.E.P. § 2164.01(b), *citing In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)). “When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification.” (M.P.E.P. § 2164.08).

Claim 1 is directed towards a method for selecting an animal for having desired genotypic properties comprising testing the animal for the presence of a parentally imprinted quantitative trait locus. When claim 1 is read in light of the as-filed specification, one of ordinary skill in the art would be able to make and use the method of claim 1 without undue experimentation.

The as-filed specification discloses that a desired genotypic property (*e.g.*, body composition, fatness, meat quality, and growth traits; *see, Specification*, as-filed, page 25, lines 25-27, page 32, lines 15-36, and page 33, lines 1-9) is linked to a parentally imprinted quantitative trait locus (*e.g.*, at chromosome 2, specifically 2p1.7; *see, Id.* at page 37, line 3).

The as-filed specification further discloses associating a phenotypic trait with the parentally imprinted quantitative trait locus and mapping the quantitative trait locus to a locus in a genome in the species of the animal. (*see, Id.* at page 37, lines 14-31, and at page 22, lines 13 to 29, page 23, line 10 to page 24, line 4, and page 33, line 30 to page 36, line 6 and further explained at page 37, line 1 to page 39, line 2). A nucleic acid sample is obtained from the animal and the nucleic acid sample is tested for the presence of the parentally imprinted quantitative trait locus as described in the as-filed specification. (*see, Id.* at page 36, lines 24-29, and at page 36, lines 7-22). When the parentally imprinted quantitative trait locus is present in the nucleic acid sample, the animal is selected as having the desired trait.

Thus, when claim 1 is read in light of the as-filed specification, once a desired genotypic property is linked to a parentally imprinted quantitative trait locus, an animal having the desired genotypic property could be selected by testing the animal for the presence of a parentally imprinted quantitative trait locus. (*see, Specification*, as-filed, at page 36, lines 7-22 and at page 39, line 25 to page 40, line 14). Accordingly, one of ordinary skill in the art would be able to make and use the method of claim 1 without undue experimentation.

Thus, reconsideration and withdrawal of the enablement rejection of claim 1 is requested.

Claims 2-9 and 36-38 are enabled as, *inter alia*, depending from an enabled base claim, claim 1.

Rejections under 35 U.S.C. § 102(b)

Claims 1, 2, 5, 8 and 36-38 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Andersson et al. and Andersson-Eklund, et al. (*See, Office Action* at page 12). Applicants respectfully traverse the anticipation rejections as hereinafter set forth.

Andersson et al. and 35 U.S.C. § 102(b)

Andersson et al. does not disclose each and every element of any of claims 1, 2, 5, 8, and 36-38. For instance, Andersson et al. does not disclose testing an animal for the presence of parentally imprinted QTL as recited in claim 1. Andersson et al. describes a QTL allele on chromosome 4, wherein the QTL allele was inherited from the Wild Boar founder animal and exhibited some degree of dominance. (*See, Andersson et al.*, Abstract and page 1772).

However, “dominance” is not identical to parental imprinting since a dominant allele is one that influences the phenotype even if it is present in only one copy, meaning that the phenotype appears the same in both the heterozygous and homozygous states. In contrast, parental imprinting is the phenomenon that gives rise to differential expression of paternally and maternally inherited alleles of certain genes due to sex-specific epigenetic differences inherited from the germline. In genomic imprinting, the expression of an allele depends on whether it was inherited through an egg or a sperm.

Thus, other than in a dominant trait where the characteristics of the carrier parent are reflected in all offspring, the parentally imprinted trait results in the trait of one parent being expressed in the offspring, irrespective of whether the genes involved are dominant or recessive. Accordingly, Andersson et al. does not describe testing an animal for the presence of a parentally QTL and cannot anticipate claim 1.

Claims 2, 5, 8 and 36-38 are not anticipated, *inter alia*, as depending from a non-anticipated base claim.

Reconsideration and withdrawal of the anticipation rejections of claims 1, 2, 5, 8 and 36-38 are requested.

Andersson-Eklund et al. and 35 U.S.C. § 102(b)

Andersson-Eklund et al. does not disclose each and every element of any of claims 1, 2, 5, 8, and 36-38. For instance, Andersson-Eklund et al. does not disclose testing an animal for the presence of a paternally imprinted QTL as recited in claim 1. Rather, Andersson-Eklund et al. discloses non-sex-linked QTLs at chromosomes 2 and 4. (*See*, Andersson-Eklund, et al., at page 699). Andersson-Eklund et al. states that the authors “did not find any significant interaction between the QTL and fixed effects of sex or CRC class,” and that testing for such interactions or “epistatic effects” would have been “unfeasible in the present study.” (*Id.*). Since Andersson-Eklund et al. does not disclose each and every element of claim 1, claim 1 cannot be anticipated.

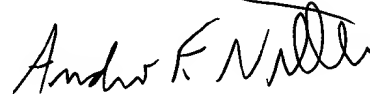
Claims 2, 5, 8 and 36-38 are not anticipated, *inter alia*, as depending from a non-anticipated base claim.

Reconsideration and withdrawal of the anticipation rejections of claims 1, 2, 5, 8, and 36-38 are requested.

CONCLUSION

In view of the foregoing amendments and remarks, the claims define patentable subject matter and a notice of allowance is requested. If any questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Andrew F. Nilles". The signature is written in a cursive, flowing style.

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